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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,089	10/26/2000	John Bertin	07334-136001	3454

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EXAMINER	
BUGAISKY, GABRIELE E	
ART UNIT	PAPER NUMBER
1653	11

DATE MAILED: 05/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/697,089	Applicant(s) ROBISON ET AL.	
	Examiner Gabriele E. BUGAISKY	Art Unit 1653	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *8-11,13-17 and 19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-7, 12 18* is/are rejected.

7)☐ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 9 is acknowledged.

Claims 8-11, 13-17 and 19-23 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Specification

The disclosure is objected to because of the following informalities: The ATCC numbers (e.g., page 7, lines 25, 31, 34, etc) are blank.

Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

No papers could be found for the IDS of 2/14/02, other than the entry on the file wrapper that a supplemental IDS was submitted. Please supply the references.

Claim Rejections – 35 U.S.C. 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to as failing to provide an adequate written description and enablement for practicing the claimed invention because the application contains at numerous pages (e.g., pages 7+ of the present specification) references to deposited biological material but only contains "ATCC ____". It is not readily apparent that the identical materials are reproducible from the instant application as to the genetic material and/or the encoded polypeptide nor to unspecified and/or allelic variants thereof. These deposited materials are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the organism is not so obtainable or available, the requirement of 35 U.S.C. 112 may be satisfied by a deposit of the microorganisms/cells.

Insofar as applicant has incorporated specific references into the specification does not eliminate the issue of public availability and permanence as the vectors cited in the references and the references *per se* do not indicate public availability of the starting materials inasmuch as the biological materials mentioned in a publication may be proprietary and not publicly available.

The specification does not disclose a repeatable process to obtain the microorganisms/cells containing and expressing the appropriate polypeptides nor is it apparent that the materials are readily available to the public. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strains have been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent and a receipt showing

that the appropriate biological material was received and entered into the depository, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 applicants may provide assurance of compliance by an affidavit or declaration, or by statement by an attorney of record over his or her signature and registration number indicating that:

a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

d) a test of the viability of the biological material at the time the deposit was made and that such test result indicated that said biological material was viable (see 37 C.F.R. 1.807); and,

e) the deposit will be replaced if it should ever become inviable.

Claim 12 is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention for the reasons indicated above.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for producing a fragment of at least 15 residues nor for any of item c) in claim 12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with this claim as directed to any and all fragments and allelic variants.

In this regard, the application disclosure and claim have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include the nature of the invention; the breadth of the claims; the

predictability or unpredictability of the art; the amount of direction or guidance presented; the presence or absence of working examples; the quantity of experimentation necessary; the state of the prior art; and, the relative skill of those skilled in the art.

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1) the nature of the invention - The instant claim is directed to a process of producing a protein where the materials necessary to practice the claimed invention which includes (in the claim) undefined fragments and undefined allelic variants. In this regard, it is not apparent from the claim that the biological activity of the protein is retained when produced by the process. Attention is also directed to the absence of enabling disclosure for reproducing the materials needed to practice the process of claim 12.

2) the breadth of the claims - The scope of the claims is broad, covering all fragments and allelic variants which have not been disclosed nor described in such a way that they are reproducible from the instant specification.

3) the predictability or unpredictability of the art and the amount of direction or guidance presented, i.e., the absence of working examples - In this instance, the application does not appear to provide disclosure that effects prediction of function for the fragments nor for function of allelic variants. Note the absence of disclosure to support the generic term in the claim. For example page 28+ refers to percent identity/homology but function is not necessarily predictable from sequence alone nor from the instant application and it would appear from the instant application specification that there is no disclosure of what are the fragments nor is there any apparent enabling disclosure for any allelic variant. There are no apparent working examples supporting fragments and allelic variants.

4) the quantity of experimentation necessary is high in view of items 1-3 above.

5) the state of the prior art – In view of items 1-4, the state of the art regarding CARD12 encoding nucleic acids does not provide for any missing disclosure regarding fragments and/or allelic variants.

6) Even where the relative skill of those skilled in the art is high, being that of at least a PhD with several years of postdoctoral experience.

In consideration of each of factors, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application

disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue and claim 12 is not enabled for fragments, and allelic variants (note that it is not apparent, if there are allelic variants, which one is the "wildtype").

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Adams *et al.* (AG). The reference is a GENBANK entry (AQ309404) which is deemed anticipatory for the claimed subject matter of claim 1b, 1d and 1e because the complement of nucleotides 2-552 is 100% identical to nucleotides 1462-2012 of SEQ ID NO:1. . Because the clone of Adams *et al.* is contained in the vector pBELOBAC11, it is deemed anticipatory for the vector nucleic acids of claims 3-4. The vector sequences themselves encode polypeptides heterologous to SEQ ID NO:2. With respect to the host cells of claim 5, the vector is propagated in host cells.

Claims 1, 3-5 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams *et al.*. The reference is a GENBANK entry (AQ112439) which is deemed anticipatory for the claimed subject matter of claim 1b, 1d and 1e because nucleotides 485-630 are 100% identical

to nucleotides 2349-2494 of SEQ ID NO:3 . .Because the clone of Adams *et al.* is contained in the vector pBELOBAC1 , it is deemed anticipatory for the vector nucleic acids of claims 3-4. The vector sequences themselves encode polypeptides heterologous to SEQ ID NO:2. . With respect to the host cells of claim 5, the vector is propagated in host cells.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams *et al.* . (AG). The reference is discussed above. It is not clear that the host cells are non-human mammalian host cells. It, however, is a design choice to use any cell type for propagation of a vector.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams *et al* (AQ112439).). The reference is discussed above. It is not clear that the host cells are non-human mammalian host cells. It however, is a design choice to use any cell type for propagation of a vector.

Conclusion

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 8:15 AM to 12:15 PM on Mondays and from 8:15 AM to 1:15 PM on other weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Gabriele E. Bugaisky
Patent Examiner
May 6, 2002

GABRIELLE BUGAISKY
PATENT EXAMINER